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Vaccine security: ensuring a sustained, uninterrupted supply of affordable vaccines

Summary

The world is experiencing vaccine shortages serious enough to risk reducing the effectiveness of immunization programmes. This is especially grave for the world's poorest countries, many of which rely on UNICEF for purchasing their vaccines, either through UNICEF country programmes of cooperation or their own funding, most of which is provided by donors.

Major developments in the vaccine industry, including the stopping of production of some vaccines by major pharmaceutical companies in the search for greater profitability, have accelerated this changing environment. Industrialized countries are now using different vaccines than those used in developing countries, which has eroded the basis on which UNICEF has bought vaccines at low prices in the past.

UNICEF has to change fundamentally its procurement position, with greater emphasis on ensuring vaccine security for the poorest nations. This has implications for the way UNICEF evaluates vaccines and the contract offers made by industry, and heralds the start of firm future contracting of vaccines. Firm contracting which ensures the availability of vaccines will require far greater emphasis on accurate forecasting of demand, as well as firm long-term pledges of financial resources to cover contractual obligations.

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I. Introduction

A. Background

1. The present report was prepared as a follow-up to the Executive Board's discussion of UNICEF activities in immunization at its annual session in June 2001 (E/ICEF/2001/6 (Part II), paras. 122-132). During that discussion, delegations encouraged the UNICEF Supply Division to expand its work in global vaccine security, and the secretariat agreed to report to the Board at its first regular session of 2002 on options for action in that area.

B. Vaccine shortages

2. Vaccine shortages have become a global problem, affecting industrialized and developing countries alike, due to significant changes in the vaccine market and the industry's greater focus on profitability. For UNICEF, which is a major purchaser of vaccines for developing countries, especially the poorest, it is increasingly difficult to ensure the supply of even the traditional vaccines that it has been purchasing for many years.

3. The supply of vaccines plays a crucial role in achieving successful results in immunization and saving children's lives. This is directly relevant to the UNICEF medium-term strategic plan (MTSP) for 2002-2005 (E/ICEF/2001/13 and Corr.1), which includes immunization "plus" as one of five programme priorities, building on more than 50 years of UNICEF experience in supporting the development of immunization services and campaigns.

4. Vaccine security — the sustained, uninterrupted supply of affordable vaccines, especially for the poorest countries — is one of the central strategies of the MTSP. Vaccine security hinges on three factors: (a) guaranteed procurement of vaccines through firm contracts with manufacturers; (b) sure future funding to cover vaccine requirements; and (c) long-term accurate forecasting of these requirements.

5. The current report: (a) identifies why vaccine security has become critical at the start of a new century and reviews the primary elements of vaccine security; and (b) sets out four steps UNICEF will take during the period 2002-2005 to influence, in its own approaches and decisions, the availability of vaccines for developing countries, particularly those that rely on UNICEF for procurement. First, however, it reviews the historical and current participation of UNICEF in the international vaccine market.

II. The role of United Nations Children's Fund in vaccine procurement

6. UNICEF meets around 40 per cent of the global demand for children's vaccines, making it a dominant participant in the international vaccine market.[1] It is important to recognize, however, that UNICEF procurement currently accounts for

[1] UNICEF buys vaccines on the international market from manufacturers specifically qualified by the World Health Organization (WHO).

around 5 per cent of the value of this market. In 2000, UNICEF procured over 2 billion doses of vaccine for nearly 100 developing countries, over 70 of which are among the world's poorest with a gross national product per capita of less than $1,000, with a birth cohort of 40 million.[2]

7. UNICEF purchases vaccines on its own behalf, using its own funds (regular and other resources) for use in programmes of cooperation with Governments. Alternatively, and increasingly more commonly, UNICEF purchases vaccines on behalf of its government partners in programme countries, using the Government's own funding (which often originates in bilateral or multilateral donor support). This facility, known as Procurement Services, is also available to other organizations in the United Nations system and governmental and non-governmental organizations, in accordance with UNICEF Financial Regulations and Rules (Rule 105.5). UNICEF rules and procedures for vaccine procurement apply whether UNICEF buys on its own behalf or on behalf of a procurement services customer. The UNICEF Supply Division has an expert team dedicated to vaccine procurement and delivery.

8. The four business segments covered by UNICEF vaccine procurement, differentiating between types of service approaches and countries served, are:

(a) **Traditional immunization services, disease control initiatives and outbreaks (poorest countries)**. These involve the following vaccines: diphtheria/tetanus/pertussis (DTP); tuberculosis (BCG); oral polio vaccine (OPV); tetanus toxoid (TT); measles; yellow fever; and meningitis. They are funded by UNICEF (regular and other resources) and have an estimated annual value of $40 million;[3]

(b) **Immunization services (middle-income countries)**. The vaccines provided are hepatitis B, measles/mumps/rubella (MMR) and measles/rubella, funded by Procurement Services mechanisms (programme and donor Governments), with an estimated annual value of $10 million;[3]

(c) **Polio eradication: National and Subnational Immunization Days (endemic countries)**. OPV procurement worth $100 million[3] per year is funded by UNICEF (other resources) and Procurement Services mechanisms;

(d) **Expanded immunization services (poorest countries)**. Hepatitis B, haemophilus influenzae (Hib) and yellow fever vaccines are funded by Procurement Services mechanisms, through the Global Fund for Children's Vaccines. Beginning in 2001, these are worth $100 million[3] per year.

9. Governments face vaccine security issues in all these categories. The long-term consolidation and expansion of immunization services is the primary component of immunization "plus", and this is where vaccine security is at greatest risk over the long term.

10. There are security issues with OPV, although the current projections are that requirements for vaccine will decrease after 2002, through to the post-2005 eradication era. Since 1999, the procurement of OPV has been the largest single effort of Supply Division, with well over 1 billion doses bought annually on the international market and several hundred million doses purchased locally in India.

[2] UNICEF is the principal purchaser for these countries.

[3] Figures are based on demand for 2001-2003, which is higher than in previous years.

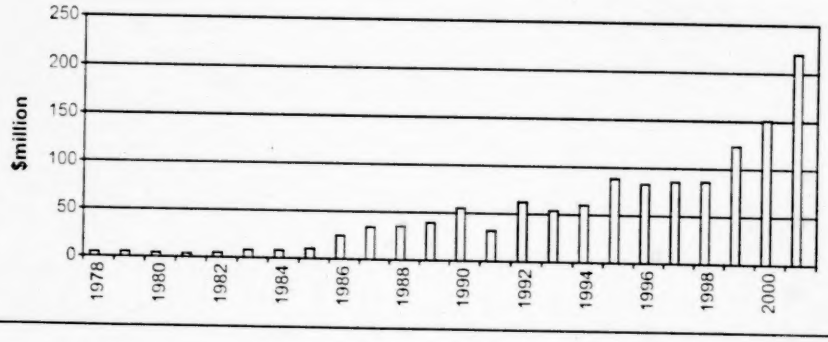
Even so, the demand for vaccine for campaigns in endemic countries has been greater than the supply available, which has caused a continuous need to adjust the activities carried out.

11. UNICEF is fully committed to polio eradication, in close collaboration with WHO, the United States Centers for Disease Control and Prevention and Rotary International, in the context of a global coalition that also includes Governments of donor and programme countries, private foundations, development banks, non-governmental humanitarian organizations and corporate partners. UNICEF will continue to place considerable emphasis on OPV supply to ensure the success of the eradication effort.

12. Expanded immunization services, the main focus of the Global Alliance for Vaccines and Immunization (GAVI), began in 2001 and are pioneering the introduction of newer and more expensive vaccines than those previously available and affordable in poorer developing countries. While the overall availability of these vaccines is adequate, there are actually shortages of the specific presentations most preferred by developing countries.[4]

13. The history of UNICEF engagement in vaccine procurement has been one of increasing numbers of products, of volume in terms of doses and of overall value, as indicated in figure 1 below:

Figure 1
Value of UNICEF Vaccine Procurement, 1978-2001
(In millions of United States dollars)



14. UNICEF has traditionally paid low prices for vaccines, as other buyers, mainly industrialized countries, have covered all production costs including the recovery of costs related to research, development and start-up capacities. Vaccine procurement by UNICEF has, nevertheless, been valued by manufacturers, because it has contributed towards overall production costs. Low prices can exist, however, only in the presence of differential pricing, in which other buyers, mainly industrialized countries, pay significantly higher prices for the same vaccines. Purchases by

[4] Most countries prefer to use vaccine presentations that blend various individual components into combination forms, substituting for older vaccines and eliminating the need to add new injections.

UNICEF at low prices effectively have been made possible by industrialized countries' procurement of the same products.

III. Emergence of the poorest countries' vaccine market

15. Since the late 1990s, this relationship has started to shift, as the poorest countries emerged as a distinct market for vaccines, driven by the divergence of immunization programmes and vaccine types, whereby industrialized countries began to use a different set of vaccines than those used in most developing countries. For example, although most developing countries continue to use whole-cell pertussis as part of the DTP combination vaccine (DTwP), higher-income countries have changed to the acellular pertussis vaccine (DTaP); the higher-priced DTaP vaccine[5] has lower yields than the whole-cell vaccine, so introduction on any scale in developing countries would require significant increases in production capacity. Similarly, high- and some middle-income countries have moved from the single-component measles vaccine to the combination MMR vaccine. Many industrialized countries have excluded BCG from their immunization programmes because of low incidence rates of tuberculosis and the vaccine's limited efficacy. Thus, DTwP, measles and BCG remain traditional vaccines for the poorest countries' market.

16. This divergence of vaccines effectively has eliminated the differential pricing from which UNICEF had benefited in the past in ensuring sustainable purchases of vaccines for developing countries at low prices. It has reduced the manufacturers' incentive to supply the high-volume markets covered by UNICEF; they are largely following the higher-priced, higher-income country markets. This is a trend seen among manufacturers in both industrialized and developing countries, although it is more noticeable in the former.

17. The emergence of the poorest countries as a distinct vaccine market has demanded a rethinking by UNICEF of its vaccine procurement. As the largest buyer for this market, UNICEF in future must take on a far greater burden in ensuring the predictability and reliability of vaccine supply. Manufacturers will depend on UNICEF in taking investment decisions on the types and amounts of vaccines they will produce for developing countries.

IV. Changes in the global vaccine industry and the response by United Nations Children's Fund

A. Changes in the vaccine industry

18. Since the late 1990s, the vaccine industry generally has shown characteristics that compromise vaccine security: consolidation by manufacturers and changes in the availability and price of vaccines.

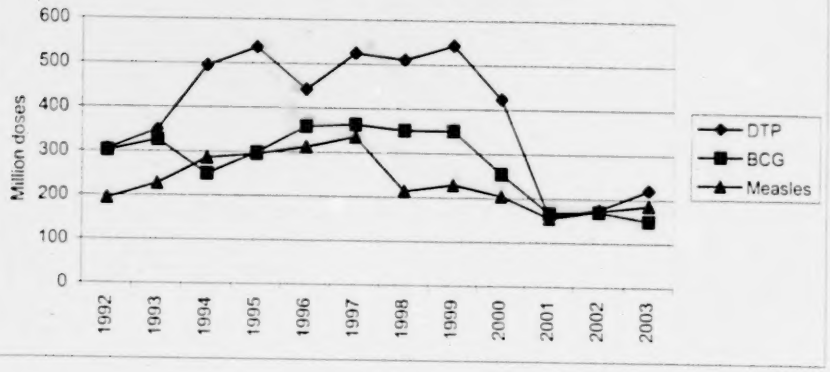
19. Between 1998 and 2001, 10 of 14 manufacturers partially or totally stopped production of traditional vaccines. Eight of these were the main suppliers to UNICEF and of the eight, six were involved in mergers between larger

[5] The average price of DTwP purchased by UNICEF in 2001 was $.07 per dose, while the price paid by CDC for DtaP was $10.65 per dose.

pharmaceutical companies seeking to broaden their product portfolios for increased profitability. Fewer manufacturers are now producing basic vaccines, so the dependency of UNICEF on a small number of manufacturers has increased in the last five years. UNICEF now buys 65 per cent of its traditional vaccines from two manufacturers in developing countries.

20. The overall result has been a dramatic decrease in the availability of vaccines to UNICEF, with the availability in 2001 of DTwP, BCG and measles vaccines at their lowest levels since the early 1990s, as indicated in figure 2 below.

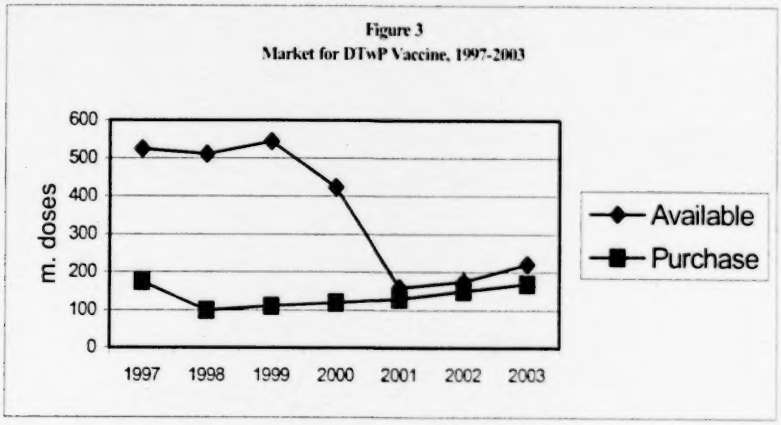
Figure 2
Availability of basic vaccines to UNICEF, 1992-2003



21. The combined effect of reduced availability of vaccines and fewer manufacturers creates a much higher risk to vaccine security as availability has become much closer to demand. This is well illustrated in the case of DTwP. As figure 3 below shows, before 2000, UNICEF only needed to buy one fifth of the available vaccine. The availability of vaccine dropped dramatically in 2000. The number of doses of DTwP which UNICEF is projected to buy over the next three years, in accordance with forecasted demand from developing countries obtaining vaccines from or through UNICEF, is now within 5 per cent of the number of doses offered to UNICEF. The closeness between supply and demand means there is no tolerance for variable yields, batch failures and slow regulatory release, which are inherent difficulties with the production of biological products.

22. Another important implication for UNICEF is the effect of market changes on vaccine prices. Prices for all basic vaccines increased between 2000 and 2001 (DTP by 15 per cent, BCG by 27 per cent, measles by 10 per cent and TT by 23 per cent) and are likely to increase more.

Figure 3
Market for DTwP Vaccine, 1997-2003



B. Firm contracting of vaccines

23. While it is difficult for UNICEF to influence manufacturers' commercial and strategic decisions related to mergers and product positioning in low-price and high-price markets, UNICEF considers that it is vital to stimulate a "healthy" vaccine industry. Given the right incentives, the industry will ensure vaccine security by producing sufficient quantities of traditional and newer vaccines at reasonable and affordable prices.

24. The single most important factor cited by vaccine manufacturers regarding their investment in research and development of new vaccines geared specifically for developing countries is the ability of those countries, with the support of UNICEF, WHO, the Bill and Melinda Gates Foundation and other partners, to accelerate the introduction and ensure the sustained use of the vaccines.

25. Beginning in 2001, UNICEF has already started longer-term organizing of vaccine procurement through three-year purchasing arrangements with manufacturers. These arrangements are not binding to either party because UNICEF does not have multi-year funding or pledges to place binding orders, although they do give manufacturers a longer-term perspective on UNICEF vaccine requirements. UNICEF will have to continue to play a significant role as a "bulk" purchaser of vaccines for many developing countries. Bulk purchasing brings economies of scale, as registration and importation costs are greatly reduced.

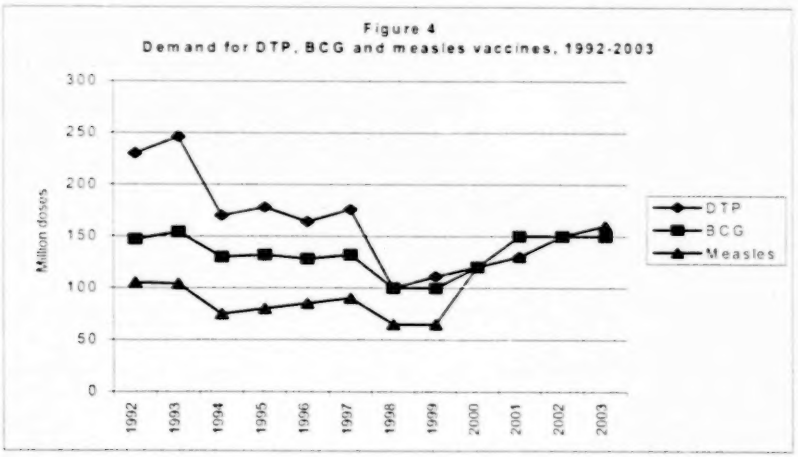
26. Given lead times of one to five years for producing vaccines and increasing production capacities, the main requirement of manufacturers is for UNICEF to be far more predictable and reliable in its vaccine procurement. To this end, in 2002 UNICEF will need to enter into firm contracts with vaccine manufacturers which will allow them to plan their capacities well in advance, assured of purchases by UNICEF. The immediate intention is to establish guaranteed purchases one year in advance and assess the results in terms of vaccine security before expanding the contracts for up to three years.

27. As is common with public-sector organizations including the Governments that receive UNICEF-procured vaccines, procurement by UNICEF is governed by principles that reinforce price as a main criterion for the evaluation of offers from manufacturers. It is becoming increasingly clear that these principles no longer apply to such markets as the one for vaccines, particularly where UNICEF commands a significant purchasing role. In this context, UNICEF will take various factors into account, in addition to price, to ensure that several manufacturers, both in industrialized and developing countries, remain fully engaged in the production of basic vaccines. These factors will include looking at the overall capacity of manufacturers and their performance in delivering vaccines on time. UNICEF will closely monitor the international vaccine market for the early identification of changes which may impact its vaccine procurement. At the same time, UNICEF will continue to work closely with WHO in the review of developing country manufacturers which produce basic vaccines but are, as yet, not pre-qualified for international procurement.

C. Sure future financing of vaccines

28. Firm contracts will need to be backed up by the timely availability of funding. As indicated in figure 4 below, demand for vaccines is increasing rapidly, particularly as a result of increased attention to the elimination of maternal and neonatal tetanus and measles control.

Figure 4
Demand for DTP, BCG and measles vaccines, 1992-2003



29. It is estimated that with the increasing demand and rising prices of vaccines, the cost of providing traditional vaccines to the poorest and middle-income countries will be around $50 million per year. Based on recent experience, it can be expected that around $10 million of this total will be funded from regular resources, another $15 million from other resources, based on specific fund-raising, and $25 million from Procurement Services mechanisms.

30. The annual funding requirements for international procurement of OPV for national campaigns are expected to remain at around $100 million for the next year,

with a gradual reduction after that, stabilizing at around $50 million per year through mid-decade. UNICEF and WHO spearhead the fund-raising drive for OPV requirements for critical needs through 2005, with significant funding from donors including the Governments of Japan and the United States.

31. In terms of newer vaccines, the GAVI mechanisms will continue to make five-year commitments to supply vaccines to eligible countries.

32. In order to ensure the timely availability of funds, UNICEF will: (a) expand its advocacy with Governments, with the aim of increasing their budgetary allocation to immunization and health; (b) enhance the scope of the Vaccine Independence Initiative (VII) Capital Fund[6] to allow more countries access to procurement services; (c) work with traditional and new donors to promote multi-year commitments for vaccines for countries that are not able to cover all costs on their own; and (d) allocate both regular and other resources to fill critical gaps.

33. UNICEF, through its Programme and Supply Divisions, will jointly monitor vaccines purchased by countries against estimated forecasts, to enable timely corrective action at country level and mobilization of outstanding resources.

34. Overall, a multifaceted approach to vaccine financing which generates multi-year allocations and pledging will give assurances of UNICEF obtaining the traditional vaccines required to sustain basic immunization services. The risk for UNICEF, if this funding strategy does not work, will be a potential further reduction in future vaccine supply, curtailing immunization programmes and ultimately risking children's lives.

D. Long-term forecasting of vaccine requirements

35. Firm contracting, backed up by sure funding, must be based on accurate forecasts of countries' demand for vaccines. As part of its commitment in the MTSP to ensure vaccine security, UNICEF will monitor and, when needed, provide technical assistance to Governments to forecast requirements for vaccines and safe injection devices, along with such other interventions as vitamin A, within the context of multi-year plans and in collaboration with WHO. The annual country forecast issued by Supply Division for completion by country offices will be the main tool for collection of data.

36. An important responsibility of countries will be to achieve high performance levels in the management of vaccines and associated products arriving in countries, ensuring that resources are put to best use, with minimum wastage rates and proper administration to avoid any adverse events. An early review of influences resulting from GAVI points to the better functioning of in-country coordination mechanisms run by Ministries of Health,[7] leading in turn to more accurate forward planning and operational decision-making, and enhancement of national capacities.

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[6] The Executive Board approved a $10 million extension of the VII in 2000 (E/ICEF/2000/P/L.47). Since its inception in 1991, there have been no defaults in repayment by countries.

[7] The Inter-agency Coordination Committee in each country brings together the Ministry of Health, UNICEF, WHO and other national and international partners in immunization support.

V. Conclusions

37. As an organization-wide priority involving headquarters and field offices, UNICEF will enhance its leadership role in the procurement and distribution of vaccines, supporting capacity-building in countries for better planning, forecasting, management and use of vaccines to provide greater predictability of demand, and acting to procure vaccines on behalf of countries as requested to ensure an affordable and uninterrupted supply of vaccines. UNICEF will:

(a) Work closely with donor countries that provide funding either directly to UNICEF or to countries which purchase vaccines through UNICEF, in order to establish ways to ensure firm pledges for funding over a multi-year period, thus allowing for greater reliability in vaccine supply;

(b) Continue to work with Governments and other partners to increase government funding and capacity for immunization services, including vaccine procurement where appropriate, both directly and through UNICEF;

(c) Enter into firm future contracts with manufacturers to ensure the availability of vaccines required for immunization services in the countries it supports;

(d) Adopt multifaceted approaches to vaccine financing to ensure that contractual obligations can be met at all times, highlighting the need to expand the VII Capital Fund to support those countries that are committed to covering their vaccine costs.